### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

	) MDL No. 1456
IN RE PHARMACEUTICAL INDUSTRY	) Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE LITIGATION	) Subcategory Case No. 06-11337
	) ) Judge Patti B. Saris
THIS DOCUMENT RELATES TO:	)
State of California, ex rel. Ven-A-Care of the Florida	) Magistrate Judge
Keys, Inc. v. Abbott Laboratories, Inc., et al.	) Marianne B. Bowler
Case No: 1:03-cv-11226-PBS	)
	)

PLAINTIFFS' RESPONSE TO DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICAL INC.'S LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT AND PLAINTIFFS' STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules of this Court, Plaintiffs, the State of California and Ven-A-Care of the Florida Keys, Inc. ("Plaintiffs), hereby submit their Response to Mylan Inc. and Mylan Pharmaceuticals Inc.'s (collectively, "Mylan") Statement of Undisputed Material Facts in Support of Mylan's Motion for Partial Summary Judgment and Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Mylan's Motion for Partial Summary Judgment. In the responses that follow, any statement submitted by Mylan that Plaintiffs do not dispute is undisputed solely for purposes of Plaintiffs' response to Mylan's motion for partial summary judgment. Plaintiffs reserve the right to dispute any such statement of fact for purposes of trial. *See* LR 56.1.

- A. Several States and the Federal Trade Commission Sued Mylan for Increasing the Price of Lorazepam and Clorazepate
- 1. On December 21, 1998, thirty-three states filed a joint complaint in the United States District Court for the District of Columbia against Mylan Inc., Cambrex Corporation, Profarmaco S.r.l., Gyma Laboratories of America, Inc. and SST Corporation in the action entitled *State of Connecticut, et. al. v. Mylan Laboratories Inc., et al.*, Civ. No. 1:98-CV-3115-TFH (D.D.C.). (*See* Palermo Decl., Ex. A, at CAMylan 04005432-3.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that on December 21, 1998, thirty-three "Litigating Plaintiff States," not including Massachusetts, filed a joint complaint in the United States District Court for the District of Columbia against Mylan Inc. *et al.* in the action entitled *State of Connecticut, et al. v. Mylan Laboratories Inc., et al.*, Civ. No. 1:98-CV-3115-TFH (D.D.C.) (the "Lorazepam Antitrust Action"). Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Lorazepam Antitrust Action's Order and Final Judgment, stating that the Complaint filed "alleg[ed] violations of the Sherman Act, Federal Trade Commission Act, and state antitrust and unfair competition and/or consumer protection laws." (Palermo Decl. Ex. A at CAMylan04005428.)

2. On the same day, the Federal Trade Commission ("FTC") filed a separate complaint (the "FTC Complaint") in the United States District Court for the District of Columbia against Mylan Inc. and the Lorazepam/Clorazepate Defendants pursuant to Section 13(b) of the Federal Trade Commission Act in the action entitled *FTC v. Mylan Laboratories Inc.*, *et al.*, Civ. No. 1:98-CV-3114-TFH (D.D.C.) (*See* Palermo Decl., Ex. B).

<u>Plaintiffs' Response</u>: Undisputed. Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the FTC Complaint, stating that the FTC Complaint filed alleged violations of the Section 5 of the Federal Trade Commission Act. (Palermo Decl. Ex. A at CAMylan04005153.)

- 3. The actions brought by the FTC and the thirty-three states were later consolidated into one proceeding entitled *In re Lorazepam & Clorazepate Antitrust Litig.*, MDL No. 1290 (TFH), Misc. No. 99ms276 (TFH) (D.D.C.) (the "Lorazepam/Clorazepate Action"). (Palermo Decl., Ex. A).
  - <u>Plaintiffs' Response</u>: Undisputed.
- 4. The states' joint complaint, as amended on February 1, 2001 (the "Joint Third Amended Complaint"), alleged that the states acted "by and through their Attorneys General...on behalf of their respective States' general economies in their sovereign capacities; and/or in their proprietary capacities on behalf of department bureaus and agencies of state government...as *reimbursers under state Medicaid* and other programs." (Palermo Decl., Ex. C, at ¶7 (emphasis added).)

Plaintiffs' Response: Disputed. Plaintiffs state that the cited reference does not support the Defendants' assertions of this paragraph. Plaintiffs do not dispute that the Joint Third Amended Complaint was filed on February 1, 2001. Further responding, Plaintiffs counter-designate and incorporate by reference the full text of the Joint Third Amended Complaint at ¶ 7 as set forth in Palermo Decl., Ex. C and clarifies the Defendant's misquoted reference as follows (in relevant part): "[t]he States bring this action by and through their Attorneys General ... as parens patriae on behalf of, natural persons; in their sovereign capacities on behalf of their respective states' general economies; and in their proprietary capacities on behalf of departments, bureaus and agencies of state government ... as reimbursers under medical or pharmaceutical reimbursement programs." (See Palermo Decl. Ex. C ¶ 7 (emphasis added).)

5. California joined in and adopted each of the allegations in the Joint Third Amended Complaint. (Palermo Decl., Ex. C, at ¶¶ 104-105.) Moreover, California specifically alleged that the Mylan's practices were in violation of California's consumer protection statute and California's antitrust statute. (Palermo Decl., Ex. C, at ¶¶ 104-105.)

Plaintiffs' Response: Disputed. Plaintiffs do not dispute that it joined in the Joint Third Amended Complaint, that it realleged paragraphs 1-95 of that Complaint, and that those paragraphs alleged that Mylan violated Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. (See Palermo Decl. Ex. C at CAMylan04005543.) Plaintiffs further do not dispute that it alleged that the "Defendants [Mylan et al.] were in violation of the Cartwright Act, California Business and Professions Code Sections 16700 et seq., and the California Unfair Competition Act, California Business and Professions Code Sections 17200 et seq." (Palermo Decl. Ex. C ¶105, CAMylan04005568-69.) Further responding, Plaintiffs state that none of the claims alleged in the Joint Third Amended Complaint are related to the present action. Compare Palermo Decl. Ex. C with First Amended Complaint in this action (Docket No. 1679).

6. The Joint Third Amended Complaint further alleged that "[i]n 1997, Mylan [Inc.] embarked on a strategy to raise the prices of some of its generic drugs and maintain these

prices at inflated levels, thereby increasing the profitability of these drugs." (Palermo Decl., Ex. E [sic], at  $\P$  35.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at  $\P$  19.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[i]n 1997, Mylan [Inc.] embarked on a strategy to raise the prices of some of its generic drugs and maintain these prices at inflated levels, thereby increasing the profitability of these drugs." (See Palermo Decl. Ex. C ¶ 35 (CAMylan04005552).) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Palermo Decl., Ex. C, stating that the Joint Third Amended Complaint, paragraph 35 continues, alleging "[o]ne part of [Mylan's] strategy was to seek from its API [Active Pharmaceutical Ingredient] suppliers long-term exclusive licenses for the DMFs [Drug Master File] of certain APIs selected by Mylan because of limited competition. If Mylan obtained such an exclusive license, no other generic drug manufacturer could use that supplier's API to make the drug in the United States." (Id. at CAMylan04005552-53.) Moreover, Plaintiffs state that the Joint Third Amended Complaint allegations of Mylan's price inflation scheme relate to the manner and method that Mylan attempted to obtain exclusive licenses from API suppliers. (See id. ¶¶ 35, 39 ("In return for the ten-year exclusive licenses, Mylan offered to pay [API suppliers] a percent of its gross profits on its sales of lorazepam..."); ¶ 42 ("In separate agreements, Mylan agreed to pay [an API supplier] a percentage of Mylan's gross profits on the sale of lorazepam ...").) By inflating its price of the final product, in this case lorazepam and clorazepate, Mylan conspired with the API suppliers, rewarding them with larger profits and enabling them to inflate API prices. (Id. ¶ 44 ("Mylan and [an API supplier] conspired and reached an agreement to fix, raise or stabilize the prices of lorazepam API."); see also id. ¶ 48.) Additionally, California asserts that the price inflation referred to the Joint Third Amended Complaint relates to the actual price of lorazepam and not lorazepam's reported prices (i.e.,

AWPs and WACs) which are at issue in the present case. Plaintiffs do not dispute that the FTC Complaint alleged "[i]n 1997, Mylan embarked on a strategy to raise the prices, and thereby increase the profitability of some its generic drugs by seeking from its API suppliers long term exclusive licenses for the DMFs of certain APIs selected by Mylan because of limited competition. If Mylan obtained such an exclusive license, no other generic drug manufacturer could use that supplier's API to make the drug in the United States." (Palermo Decl. Ex. B ¶19 (CAMylan04005153).)

7. The Joint Third Amended Complaint further alleged that "[t]he acts and practices of the Defendants...have had the purpose or effect...to restrain competition unreasonably and to injure competition...." (Palermo Decl., Ex. C, at ¶ 51.) The FTC Complaint alleged similar allegations. (Palermo Decl., Ex. B, at ¶ 34.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[t]he acts and practices of the Defendants...have had the purpose or effect...to restrain competition unreasonably and to injure competition...." (Palermo Decl. Ex. C ¶ 51.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Palermo Decl., Ex. C and states that the focus of the Joint Third Amended Complaint's above referenced allegation relates primarily to the Defendant's conduct regarding APIs. (See id. ¶¶ 52-56.) Plaintiffs do not dispute that the FTC Complaint contained similar allegations. (See Palermo Decl. Ex. B ¶ 34.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the FTC Complaint as set forth in Palermo Decl., Ex. B and states that the focus of the FTC Complaint's above referenced allegation relates primarily to the Defendant's conduct regarding APIs. (See id. ¶ 34a-d.)

8. The Joint Third Amended Complaint further alleged that "one part of [Mylan Inc.'s] [alleged] strategy" involved improper agreements for the supply of active pharmaceutical ingredients. (Palermo Decl., Ex. C, at ¶ 35.) The FTC Complaint states similar allegations. (Palermo Decl., Ex. B, at ¶¶ 32, 33.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[o]ne part of [Mylan's] strategy was to seek from its API [Active Pharmaceutical Ingredient] suppliers long-term exclusive licenses for the DMFs [Drug Master File] of certain APIs selected by Mylan because of limited competition. If Mylan obtained such an exclusive license, no other generic drug manufacturer could use that supplier's API to make the drug in the United States." (See Palermo Decl. Ex. C ¶ 35 (CAMylan04005552-53).) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Plaintiffs incorporate herein by reference their response to SOF 6. Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

9. The Joint Third Amended Complaint further alleged that on "January 12, 1998 despite no significant increase in its costs, Mylan [Inc.] raised its price of Clorazepate tablets...by amounts ranging from 1,900 percent to over 3,200 percent, depending on the bottle size and strength. For example, a 500-count bottle of 7.5 mg Clorazepate tablets increased in price from \$11.36 to \$377.00. The ultimate retail price to consumers was even higher" and on "March 3, 1998, despite no significant increase in its costs, Mylan [Inc.] raised its price of Lorazepam tablets by amounts ranging from 1,900 percent to over 2,600 percent, depending on the bottle size and strength. For example, a 500-count bottle of Img Lorazepam tablets increased in price from \$7.30 to \$191.50. The ultimate retail price to consumers was even higher." (Palermo Decl., Ex. C, at ¶ 45 (emphasis added).) The FTC complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 28.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that on "January 12, 1998 despite no significant increase in its costs, Mylan [Inc.] raised its price of Clorazepate tablets...by amounts ranging from 1,900 percent to over 3,200 percent, depending on the bottle size and strength. *For example, a 500-count bottle of 7.5 mg Clorazepate tablets increased in price from \$11.36 to \$377.00*. The ultimate retail price to consumers was even higher" and "[o]n March 3, 1998, despite no significant increase in its costs, Mylan [Inc.] raised its price of lorazepam tablets by amounts ranging from 1,900 percent to over 2,600 percent, depending on the bottle size and strength. For example, a 500-count bottle of 1

mg lorazepam tablets increased in price from \$7.30 to \$191.50. The ultimate retail price to consumers was even higher." (*See* Palermo Decl. Ex. C ¶ 45.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Plaintiffs incorporate herein by reference its response to SOF 6. Plaintiffs dispute all other parts of this statement as not supported by the materials cited. Plaintiffs do not dispute that the FTC complaint stated the same allegations. (*See* Palermo Decl. Ex. B  $\P$  28.)

10. The Joint Third Amended Complaint further alleged that "[o]n January 12, 1998...Mylan raised its price of clorazepate tablets to State Medicaid programs", that "[o]n March 3, 1998...Mylan raised its price of Lorazepam tablets", and that "[a]fter the abovementioned price increases were effected, departments, bureaus, or agencies of the governments of some States (or such States' assignors) purchased Lorazepam or Clorazepate tablets at supracompetitive prices from Mylan [Inc.] or its subsidiaries...." (Palermo Decl., Ex. C, at ¶ 45.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 29.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[o]n January 12, 1998...Mylan raised its price of clorazepate tablets to State Medicaid programs..." (See Palermo Decl. Ex. C at ¶ 45.) Plaintiffs further do not dispute that the Joint Third Amended Complaint alleged that "[o]n March 3, 1998...Mylan raised its price of lorazepam tablets", and that "[a]fter the above-mentioned price increases were effected, departments, bureaus, or agencies of the governments of some States (or such States' assignors) purchased lorazepam or clorazepate tablets at supra-competitive prices from Mylan [Inc.] or its subsidiaries...." (Id.) Plaintiffs also counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Additionally, Plaintiffs incorporate herein by reference their response to SOF 6. Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

11. The Joint Third Amended Complaint alleged increases in market share and profits to Mylan Inc. derived from sales to many different types of customers, including

"pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, patients, consumers, and others...." (Palermo Decl, Ex. C, at ¶ 47.)

Plaintiffs' Response: Disputed. Plaintiffs state that the cited references do not support the Defendants' assertions of this paragraph. Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[a]s a result of these substantial and unprecedented agreements and price increases for lorezapam and clorazepate tablets, many purchasers, including pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, patients, consumers and others, have paid substantially higher prices." (*See* Palermo Decl. Ex. C ¶ 47.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Plaintiffs further state that nowhere in paragraph 47 of the Joint Third Amended Complaint do the allegation address increases to Mylan's market share and/or profits. (*Id.*)

12. The Joint Third Amended Complaint further alleged that the effect of the increase in the AWP and WAC prices of Mylan's Lorazepam/Clorazepate raised "the cost that...government agencies...pay for Lorazepam and Clorazepate tablets." (Palermo Decl. Ex. C, at ¶ 54, see also ¶¶ 104, 105 (emphasis added).)

Plaintiffs' Response: Disputed. Plaintiffs state that the cited reference does not support the Defendant's assertion of this paragraph. Plaintiffs do not dispute that the Joint Third Amended Complaint at paragraphs 51 and 54 alleged that "[t]he acts and practices of the Defendants as herein alleged have had the purpose or effect... to restrain competition unreasonably and injure competition within each State" by, among other things, "[r]aising the cost that pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, consumers, and others pay for lorazepam and clorazepate tablets;" (See Palermo Decl. Ex. C ¶¶ 51, 54.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Palermo Decl., Ex. C

and states that the Joint Third Amended Complaint does not contain any allegations that mention AWP or WAC prices for any of Mylan's products. (*Id.*)

13. The Joint Third Amended Complaint further alleged that "[a]s a result of these substantial and unprecedented agreements and price increases for Lorazepam and Clorazepate tablets, many purchasers, including...government agencies...have paid substantially higher prices." (Palermo Decl., Ex. C, at ¶ 47.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 31.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[a]s a result of these substantial and unprecedented agreements and price increases for lorezapam and clorazepate tablets, many purchasers, including pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, patients, consumers and others, have paid substantially higher prices." (See Palermo Decl. Ex. C ¶ 47.) Plaintiffs also counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Palermo Decl., Ex. C. Plaintiffs cannot respond to Defendant's Statement regarding the FTC Complaint, paragraph 31 because the copy of that document served on the Plaintiffs is illegible at paragraph 31. Additionally, Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

14. The Joint Third Amended Complaint further alleged that the anticompetitive effects alleged against Mylan Inc. included: "[r]aising the cost that...government agencies...pay for Lorazepam and Clorazepate tablets." (Palermo Decl., Ex. C, at ¶ 54.) The FTC complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 47.)

<u>Plaintiffs' Response</u>: Disputed. Plaintiffs state that the cited reference does not support the Defendant's assertion of this paragraph. Plaintiffs do not dispute that the Joint Third Amended Complaint at paragraphs 51 and 54 alleged that "[t]he acts and practices of the Defendants as herein alleged have had the purpose or effect... to restrain competition unreasonably and injure competition within each State" by, among other things, "[r]aising the cost that pharmacies, hospitals, insurers, managed care organizations, wholesalers, government

agencies, consumers, and others pay for lorazepam and clorazepate tablets;" (*See* Palermo Decl. Ex. C ¶¶ 51, 54.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Again, Plaintiffs cannot respond to the Defendant's Statement regarding the FTC Complaint, paragraph 47, because the copy of that document served on Plaintiffs is illegible at paragraph 47. Additionally, Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

15. The Joint Third Amended Complaint further alleged that "[a]s a direct and proximate result of the unlawful conduct alleged above, the States were not and are not able to...pay reimbursements for purchases of Lorazepam and Clorazepate at prices determined by free and open competition...and have paid more and continue to pay more...than they would have paid in a free and open competitive market" and that Mylan Inc. "unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits." (Palermo Decl., Ex. C, at ¶ 57-60 (emphasis added).) The FTC Complaint alleged similar allegations. (Palermo Decl., Ex. B, at ¶ 30-31, 34.)

Plaintiffs' Response: Plaintiffs do not dispute that the Joint Third Amended Complaint alleged that "[a]s a direct and proximate result of the unlawful conduct alleged above, the States were not and are not able to purchase, or pay reimbursements for purchases of, lorazepam and clorazepate at prices determined by free and open competition, and consequently have been injured in their business and property in that, *inter alia*, they have paid more and continue to pay more for lorazepam and clorazepate than they would have paid in a free and open competitive market." (Palermo Decl. Ex. C ¶ 57.) Plaintiffs also do not dispute that the Joint Third Amended Complaint alleged that "[a]s a direct and proximate result of the unlawful conduct alleged above, the Defendants have unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits." (Palermo Decl. Ex. C ¶ 60.) Plaintiffs also counter-designate and incorporate herein by reference the full text of the Joint Third Amended Complaint as set forth in Exhibit C. Again, Plaintiffs cannot respond to the Defendant's

Statement regarding the FTC Complaint, paragraphs 30, 31, and 34 because the copy of that document served on the Plaintiffs is illegible at paragraphs 30, 31, and 34. Additionally, Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

## B. Mylan and California Agree to Settle the Lorazepam/Clorazepate Action

16. On January 30, 2001, after "extensive analysis of the pertinent facts" and "extensive arms-length negotiation," Mylan Inc., the FTC and the various states entered into an agreement entitled the "Settlement Agreement Between Plaintiff States, The Federal Trade Commission And Mylan Laboratories, Inc., GYMA Laboratories Of America, Inc., Profarmaco S.R.L., Cambrex Corp." (the "Lorazepam/Clorazepate Settlement"). (Palermo Decl., Ex. D, at CaMylan04005202- 5203.)

Plaintiffs' Response: Undisputed.

17. California was a party to the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. D, at Section I(N) at CAMylan 04005207.)

Plaintiffs' Response: Undisputed.

18. In Section IV(A) of the Lorazepam/Clorazepate Settlement, Mylan Inc. agreed to pay \$100 million in full and final settlement of the claims asserted against Mylan Inc. in exchange for the release of all Released Claims, as defined in Section I(U) of the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. D, at Section IV(A) at CAMylan 04005211.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Lorazepam/Clorazepate Settlement, §IV(A) stated that Mylan "has agreed to pay \$100 million in cash in full and final settlement of the claims against all Settling Defendants as set forth in the [FTC] Complaint and in the [Joint Third Amended] Complaint and in exchange for the release of all Released Claims." (Palermo Decl. Ex. D § IV(A) (CAMylan 04005211).)

19. In the Lorazepam/Clorazepate Settlement, California agreed to "release[] and "forever discharge[]" Mylan Inc. and all of its subsidiaries and affiliates from:

[A]ll claims, counterclaims, set-offs, demands, actions, rights, liabilities, and causes of action arising under federal or state antitrust, unfair methods of competition, or consumer protection laws, under state or federal unfair or deceptive trade practices acts, or under common law, asserted or that could have been asserted...by the Plaintiff States on behalf of state

agencies...arising from the facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions, or failures to act set forth or alleged in the [Joint Third Amended Complaint]....

(Palermo Decl., Ex. D, at Sections I(U), I(Y), and IV(D).)

Plaintiffs' Response: Undisputed.

20. In the Lorazepam/Clorazepate Settlement, California agreed to the dismissal with prejudice of its claims in the Joint Third Amended Complaint. (Palermo Decl., Ex. D, at Section VII(C) and Attachment 2.)

Plaintiffs' Response: Plaintiffs do not dispute that California agreed to dismiss the Joint Third Amended Complaint with prejudice. (*See* Palermo Decl. Ex. D §§ VI(A), VI(B)(1).) Further responding, Plaintiffs do not dispute that "[t]he [FTC], Plaintiff States, and Settling Members of the Settlement Group are barred from further prosecution of the Released Claims, and Settling Defendants and SST Settling Defendant are released and forever discharged from liability for the Released Claims." (*Id.* § VI(A).)

21. Nothing in the terms of the Lorazepam/Clorazepate Settlement required Mylan to change the prices for its Lorazepam/Clorazepate products or to change its pricing practices. (*See generally* Palermo Decl., Ex. D.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Lorazepam/Clorazepate Settlement did not address or require Mylan to change the prices or pricing practices for its lorazepam or clorazepate products. (*See* Palermo Decl. Ex. D.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Order and Final Judgment as set forth in Exhibit A and the Settlement as set forth in Exhibit D, and states that the Settlement contained, and the Order and Final Judgment acknowledged a "Stipulated Permanent Injunction." (Palermo Decl. Ex. D; *see also* Palermo Decl. Ex. A at Attachment 4.) Plaintiffs state that the "Stipulated Permanent Injunction," in part, enjoined Mylan from engaging in the anticompetitive conduct which was the basis of the antitrust litigation. (Palermo Decl. Ex. A, at

Attachment 4 (CAMylan04005324-31).) Plaintiffs assert that the Settlement is devoid of terms limiting Mylan's pricing practices because the Lorazepam/Clorazepate cases were based on anticompetitive conduct via exclusive licenses with API suppliers. The price inflation alleged in the Lorazepam/Clorazepate case was related to Mylan's collusive market activity and referred to real transaction prices, not false reported prices (AWP and WAC) as alleged in the present case.

22. The terms of the Lorazepam/Clorazepate Settlement state that the settlement is governed by New York law. (Palermo Decl., Ex. D, at Section XI(H).)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Lorazepam/Clorazepate Settlement stated that "[t]his Settlement Agreement, including, but not limited to, the releases contained herein, shall be governed by, and construed in accordance with, the laws of the State of New York without regard to its conflict of laws principles." (Palermo Decl. Ex. D § XI(H) (CAMylan04005223-24).)

23. On February 1, 2001, the Lorazepam/Clorazepate Settlement was filed with the District Court for the District of Columbia. (*See generally* Palermo Decl., Ex. A.)

Plaintiffs' Response: Undisputed.

24. On February 1, 2001, California joined in a request with the other states for approval of the Lorazepam/Clorazepate Settlement. (*See* Palermo Decl., Ex. A, at Sections II(U), (T).)

Plaintiffs' Response: Undisputed.

25. On April 27, 2001, the District Court of the District of Columbia preliminarily approved the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. E.)

<u>Plaintiffs' Response</u>: Undisputed.

26. The Lorazepam/Clorazepate Settlement including the release contained therein "shall be governed by, and construed in accordance with the laws of the State of New York without regard to its conflict of laws principles." (Palermo Decl., Ex. D, at Section XI(H).)

Plaintiffs' Response: Undisputed.

- C. The Lorazepam/Clorazepate Settlement is Finally Approved and Judgment is Rendered in the Lorazepam/Clorazepate Litigation
- 27. On February 1, 2002, the District Court for the District of Columbia entered an order and final judgment granting final approval of the Lorazepam/Clorazepate Settlement (the "Order and Final Judgment"). (Palermo Decl., Ex. A.)
  - Plaintiffs' Response: Undisputed.
- 28. The Order and Final Judgment dismissed the various states' prior complaints "with prejudice" and applied to Mylan Inc. and its affiliates (Palermo Decl., Ex. A, at Sections II(AA) and VI(A).)

Plaintiffs' Response: Plaintiffs do not dispute that the Order and Final Judgment stated that "[s]ubject to the provisions of Section IX of this Order and Final Judgment, the [FTC]'s and the Plaintiff States' Complaints are dismissed with prejudice." (Palermo Decl. Ex. A § VI(A) (CAMylan04005438-39).) Further responding, Plaintiffs do not dispute that the Order and Final Judgment states that "Settling Defendants' means Mylan Laboratories, Inc. ("Mylan")..." (Palermo Decl. Ex. A § II(AA) (CAMylan04005434).)

29. The Order and Final Judgment states that Mylan Inc. and the various states, including California, "executed a settlement agreement" in order to "resolve any and all disputes arising from the [prior complaints]." (Palermo Decl., Ex. A, at CaMylan04005428-CaMylan04005429.)

Plaintiffs' Response: Plaintiffs do not dispute that the Order and Final Judgment stated that "Plaintiff States, the [FTC] and Settling Defendants desire to resolve any and all disputes arising from the Complaints. The parties executed a settlement agreement on January 30, 2001..." (Palermo Decl. Ex. A at CaMylan04005428- CaMylan04005429.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Order and Final Judgment as set forth in Exhibit A and states that the Order and Final Judgment defines the allegations made in the Lorazepam/Clorazepate cases as "violations of the Sherman Act, Federal Trade Commission Act, and state antitrust and unfair competition and/or consumer protection laws. (*Id.*)

30. The Order and Final Judgment barred California, as one of the states parties to the Lorazepam/Clorazepate Settlement, "from further prosecution of the Released Claims" and further stated that Mylan Inc. and its subsidiaries and affiliates "are released and forever discharged from liability for the Released Claims." (Palermo Decl., Ex. A, at Section VI(A).)

Plaintiffs' Response: Plaintiffs do not dispute that the Order and Final Judgment stated that "[t]he Plaintiff States, the [FTC] and Settling Members of the Settlement Group are barred from further prosecutions of the Released Claims, and Settling Defendants and SST Defendant are released and forever discharged from liability for the Released Claims." (Palermo Decl. Ex. A § VI(A) (CAMylan04005438-39) (emphasis added).) Further responding, Plaintiffs counterdesignate and incorporate herein by reference the full text of the Order and Final Judgment as set forth in Exhibit A and states that the Order and Final Judgment defines Released Claims, in relevant part, as "all claims, counterclaims, set-offs, demands, actions, rights, liabilities, and causes of action arising under federal or state antitrust, unfair methods of competition, or consumer protection laws, under state or federal unfair or deceptive trade practices acts, or under common law, asserted or that could have been asserted by the [FTC], by Settling Members of the Settlement Group, or by the Plaintiff States on behalf of state agencies and/or natural person consumers within the Plaintiff States against Settling Defendants and SST Settling Defendant arising from facts, matters, transactions events, occurrences, acts, disclosures, statements, omissions, or failures to act set forth or alleged in the [FTC]'s Complaint or in the Plaintiff States' Complaint: (Palermo Decl. Ex. A § II(V) (CAMylan04005433-34) (emphasis added).)

31. The Order and Final Judgment dismissing the Lorazepam/Clorazepate Action "adjudicate[d] all the claims, rights and liabilities of the parties, and is final and shall be immediately appealable." (Palermo Decl., Ex. A, at Section VIII.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Order and Final Judgment stated that "[t]he Court finds that this Order and Final Judgment adjudicates all the claims, rights and

liabilities of the Parties, and is final and shall be immediately appealable." (Palermo Decl. Ex. A § VIII (CAMylan04005440-41).) Further responding, Plaintiffs counter-designate and incorporate herein by reference the full text of the Order and Final Judgment as set forth in Exhibit A and states that the Order and Final Judgment's adjudicated claims refer to the alleged "violations of the Sherman Act, Federal Trade Commission Act, and state antitrust and unfair competition and/or consumer protection laws. (Palermo Decl. Ex. A at CAMylan04005430.)

32. The Order and Final Judgment states that the "terms of the Settlement Agreements are adjudged as fair, reasonable and adequate and in the best interests of consumers in the Plaintiff States and the Settlement Group as a whole, and satisfy the requirements of Federal Rule of Civil Procedure 23(e), state *parens patriae* laws and/or state equitable authority and due process." (Palermo Decl., Ex. A, at Section IV(C).)

Plaintiffs' Response: Undisputed.

#### D. Mylan Completed Its Obligations Under the Lorazepam/Clorazepate Settlement

33. Mylan paid, through an escrow agent, "\$100 million in full and final settlement" of the Lorazepam/Clorazepate Action. This amount was divided into the Agency Account of the State Fund and the Consumer Fund. The funds from these accounts were distributed to the states. (*See* Palermo Decl., Ex. D, at Sections IV, V, and VI.)

<u>Plaintiffs' Response</u>: Plaintiffs do not dispute that the Lorazepam/Clorazepate Settlement provided for a \$100 million settlement to be divided into the Agency Account of the State Fund and the Consumer Fund and the funds from these accounts were to be distributed to the states. (*See* Palermo Decl. Ex. D.) Plaintiffs dispute all other parts of this statement as not supported by the materials cited.

34. On or about August 25, 2005, approximately three years after the final approval of the Lorazepam/Clorazepate Settlement and Mylan Inc.'s completion of its obligations under the Lorazepam/Clorazepate Settlement, California intervened in the present action. (Palermo Decl., Ex. F.)

<u>Plaintiffs' Response</u>: Undisputed as to the existence of the complaint. However, Plaintiffs dispute any characterization of the complaint as similar to the antitrust case.

### E. Mylan Inc. Is Not A Proper Party To This Action

35. California alleges that Mylan Inc. manufactured, marketed, and sold the Mylan generics during the relevant time period. (Palermo Decl., Ex. F, at ¶¶ 16, 123-128.)

<u>Plaintiffs' Response</u>: Disputed. Plaintiffs do not dispute that they allege that Mylan Laboratories, Inc. manufactured, marketed, and sold the Mylan generics during the relevant time period. (Palermo Decl. Ex. F ¶¶ 16, 123-128.) Further responding, Plaintiffs counter-designate and incorporate herein by reference the testimony of Hal Korman, wherein he states that Mylan Laboratories, Inc. recently changed its name to Mylan, Inc. (Palermo Decl. Ex. H at 70-71.)

36. Mylan Inc. is a holding company and did not manufacture, market, or sell the Mylan generics. (Palermo Decl.; Ex. H, at 70:18-71:5; Ex. G, at Response to Interrogatory No. 6.)

<u>Plaintiffs' Response</u>: Disputed. Plaintiffs do not dispute that Mylan Laboratories Inc., now known as Mylan, Inc., is the parent company of numerous subsidiaries. Further responding, Plaintiffs dispute all other parts of this statement as not consist with the following material cited. (*See* Pls.' Resp. to SOFs 37-38 below.)

37. Mylan Pharmaceuticals Inc., not Mylan Inc., manufactured and sold the Mylan generics during the relevant time period. (Palermo Decl., Ex. I, at 44:2-45:10.)

Plaintiffs' Response: Disputed. Further responding, at the time of filing the present Complaint, Mylan Laboratories Inc., now known as Mylan, Inc., attested in its Form 10-K SEC filings that it manufactured, marketed and sold generic pharmaceuticals. (*See e.g.* Declaration of Matthew Kilman ("Kilman") Declaration, Ex. 3 at 3 (Part 1, Item 1) (Mylan Laboratories Inc. ('We' 'the Company' or 'Mylan') is engaged in developing, licensing, *manufacturing, marketing and distributing generic* and brand pharmaceutical products.") (emphasis added); *see also* Kilman Decl. Exs. 1, 2 and 4.) California states that Mylan also attested that "[w]e," defined as Mylan Laboratories, Inc., "manufacture and market approximately 115 generic pharmaceuticals in capsule or tablet form in an aggregate of approximately 285 dosage strengths. (Kilman Decl.

Ex. 2 at 4.) Moreover, Mylan stated that "[i]n fiscal 2003, Mylan [defined as Mylan Laboratories, Inc.] held the first or second market position in new and refilled prescriptions dispensed among all pharmaceutical companies in the U.S. with respect to 96 of the 133 generic pharmaceutical products we marketed, excluding unit-dose products." (Kilman Decl. Ex. 3 at 4.)

38. Mylan Pharmaceuticals Inc. reported the AWP prices for the Mylan generics during the relevant time period. (Palermo Decl., Exs. J, K, L, M, N.)

Plaintiffs' Response: Disputed. Plaintiffs state that Roderick Jackson was employed by Mylan Laboratories Inc., now known as Mylan, Inc., from 1986 to May 1, 2002. (Kilman Decl. Ex. 5 at 12-13.) In 1992, Mr. Jackson was promoted to Senior Vice President of Mylan Laboratories Inc. with responsibility for sales and marketing. (Id. at 30.) According to Mylan Laboratories Inc.'s organizational charts dated September 29, 1999, employees of Mylan Pharmaceuticals Inc., including but not limited to Hal Korman, Vice President of Sales, reported directly to Mr. Jackson. (Id. at 90-91.) Mylan designated Brian Roman, its Associate General Counsel of Operations, as a Rule 30(b)(6) deposition witness. (See Kilman Decl. Ex. 8.) Roman also holds the position of Vice President and General Counsel of Mylan Pharmaceuticals, Inc. (Id. at 9-10.) Roman testified that during the relevant time period pricing authority at Mylan with regard to the drugs at issue in this case were exercised by Rod Jackson, a Senior Vice President of Mylan Laboratories, Inc. (Palermo Decl. Ex. 7 at 131-32.) Accordingly, Plaintiffs do not dispute that Mylan Pharmaceuticals Inc. acting under the direction and control of Mylan Laboratories Inc., now known as Mylan, Inc., reported AWP prices for the Mylan Generics during the relevant time period. (*Id.*; see also Kilman Decl. Ex. 5 at 88:4-14; Kilman Decl. Exs. 6-7.)

PLAINTIFFS' ADDITIONAL UNDISPUTED MATERIAL FACTS IN OPPOSITION TO DEFENDANT MYLAN'S MOTION FOR PARTIAL SUMMARY JUDGMENT

1. When compared with Medi-Cal claims data from 2000, the findings contained in

two Myers & Stauffer reports from 2002 ("A Survey of Acquisition Costs of Pharmaceuticals in

the State of California" and "Study of Medi-Cal Pharmacy Reimbursement") do not confirm, or

otherwise demonstrate, that Medi-Cal's total reimbursement payments from 1994 through 2004

resulted in only modest dollar payments above the provider's total cost. Rather, such a

comparison actually suggests that Medi-Cal's reimbursement payments were indeed

"overpayments," resulting in significant dollar payments above the provider's total cost.

(Declaration of Suzanne Graydon ("Graydon Decl.") ¶¶ 1-7 & Ex. 1.)

2. The findings of the Myers and Stauffer reports, when compared with Medi-Cal

claims data from 2000 and 2004, do not support the position that the reimbursement rate that

California adopted in 2004 continued to result in dollar margins comparable to the levels of

2000. Rather, such a comparison reveals that the reimbursement rate that California adopted in

2004 actually resulted in different dollar margins and cannot be said to be comparable to the

levels of 2000. (Graydon Decl. ¶¶ 1-7 & Ex. 1.)

Dated: December 21, 2009

Respectfully submitted,

EDMUND G. BROWN JR.

Attorney General for the State of California

By: /s/ *Matthew C. Kilman* .

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# Attorneys for Plaintiff STATE OF CALIFORNIA

## **CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy of Lexis-Nexis for posting and notification to all parties.

/s/ Matthew C. Kilman
MATTHEW C. KILMAN